

## **REMARKS**

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claims 12, 14-16 and 21-27 were pending in this application when examined.

Claims 12 and 14 have been amended to recite a composition “consisting of” a copolymer of a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500 and a polymerizable vinyl monomer in a weight ratio of 6:4 to 9:1. Claim 12 has also been amended to become an independent claim and to make minor editorial changes, which are self-explanatory.

Claim 16 has been amended to recite a binder “consisting of” a copolymer of a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500 and a polymerizable vinyl monomer in a weight ratio of 6:4 to 9:1.

Claims 23-27 have been cancelled without prejudice or disclaimer.

### **I. Restriction Requirement**

The Examiner indicates that new claims 23-27 are directed to an invention that lacks unity with the invention originally claimed. Non-elected claims 23-27 have been cancelled. Applicants reserve their rights under 35 U.S.C. § 121 to file a divisional application for the non-elected subject matter.

### **II. Claim Objection**

The Examiner objects to claim 12 under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 12 has been amended into an independent claim. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

### **III. Claim Rejections Under 35 U.S.C. § 102**

The Examiner rejects claims 14, 21 and 22 under 35 U.S.C. § 102(a) as being anticipated by Hoshi et al. (US 2003/0166763); and rejects claim 16 under 35 U.S.C. § 102(a) as being anticipated by Hoshi et al. As applied to the amended claims, Applicants respectfully traverse the rejections.

Synthesis Example 2 of the Hoshi et al. reference discloses a copolymer comprising (1) a **mixture** of PVA-SH having a polymerization degree of **500 and 1500** (a mixture of 50:50, 45:55, 40:60, 20:80 or 10:90 of 500 and 1500), and (2) acrylic acid and methyl methacrylate (see paragraph [0055] and Table 2).

Further, the reference discloses in Synthesis Example 4, a copolymer comprising (1) a **mixture** of PVA having a polymerization degree of **500 and 1700** (a mixture of 50:50, 45:55, 40:60, 20:80 or 10:90 of 500 and 1700), and (2) acrylic acid and methyl methacrylate (see paragraph [0059] and Table 4).

The Examiner states that the composition of claim 14 has the transitional phrase “comprising”, which is open-ended and does not exclude additional, unrecited elements (see Office Action, page 9, item C).

However, the transitional phrase “**consisting of**” excludes any element, step, or ingredient not specified in the claim (see MPEP 2111.03). Claim 14 has been amended to recite a composition “**consisting of** a copolymer of a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500 and a polymerizable vinyl monomer in a weight ratio of 6:4 to 9:1”; and claim 16 has been amended to recite a binder “**consisting of** a copolymer of a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500 and a polymerizable vinyl monomer in a weight ratio of 6:4 to 9:1”.

Accordingly, in claims 14 and 16, the copolymer is limited to (1) a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500, and (2) a polymerizable vinyl monomer comprising acrylic acid and methyl methacrylate.

Therefore, the composition of claim 14 and the binder of claim 16, are patentable over the compositions disclosed in the reference, because the copolymer of claims 14 and 16 are limited to (1) a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500, and (2) a polymerizable vinyl monomer comprising acrylic acid and methyl methacrylate, whereas the compositions disclosed in the reference include PVA-SH or PVA

having an average polymerization degree of more than “300 to 500”, as recited in claims 14 and 16.

Accordingly, claims 14 and 16 are not anticipated by the reference.

Claims 21 and 22 depend from claim 14, and thus also are not anticipated by the reference.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

#### **IV. Claim Rejection Under 35 U.S.C. § 103**

The Examiner rejects claims 12, 14, 15, 21 and 22 under 35 U.S.C. § 103(a) as being unpatentable over Angel et al. (US 2002/0042466). As applied to the amended claims, Applicants respectfully traverse the rejection.

Angel et al. disclose a copolymer of (a) **hydroxyl-C<sub>1</sub>-C<sub>6</sub>-alkyl (meth)acrylate**, (b) polyvinyl alcohol (the degree of polymerization is from 227 to 2270), and (c) a polymerizable compound, such as acrylic acid and methyl methacrylate (see Abstract and claim 1 of the reference). Thus, the copolymer of the reference includes **hydroxyl-C<sub>1</sub>-C<sub>6</sub>-alkyl (meth)acrylate** as an essential component.

On the other hand, the copolymer of claims 12, 14 and 16 is limited to (1) a partially hydrolyzed polyvinyl alcohol having an average polymerization degree of 300 to 500, and (2) a polymerizable vinyl monomer comprising acrylic acid and methyl methacrylate. Accordingly, the copolymer of claims 12, 14 and 16 **do not contain hydroxyl-C<sub>1</sub>-C<sub>6</sub>-alkyl (meth)acrylate**, and are thus completely different from the copolymer disclosed in the reference. Further, the reference does not suggest a copolymer, which does not include hydroxyl-C<sub>1</sub>-C<sub>6</sub>-alkyl (meth)acrylate.

In addition, the reference teaches “It is an object of the present invention to provide water-soluble or water-dispersible polymers as coating agents, binders, and/or film-forming excipients in pharmaceutical dosage forms, in particular for instant release forms, which do not have the abovementioned disadvantages” (see paragraph [0017]) (emphasis added).

On the other hand, the present specification teaches “The coating composition of the present invention containing a polyvinyl alcohol copolymer as a main component has effects of preventing oxidation of medicines, drugs for animals, agricultural chemicals, fertilizers and foods, masking an offensive smell, preventing a change in the formulation, and of preventing

bitterness” (see page 8, lines 17-22 of the substitute specification) (emphasis added).

In addition, the specification teaches that the PVA copolymer of the present invention has the excellent effect of suppressing a whisker formation by film-coating on a pharmaceutical preparation having sublimation property, and teaches that “unclearness of an embossed mark accompanied with floating (bridging phenomenon)” is not seen in the PVA copolymer of the present invention (see page 9, lines 18-20, page 18, lines 26-27 and Example 1 of the substitute specification).

Accordingly, the effects and purpose of the claimed composition and binder are quite different from the reference.

Therefore, claims 12, 14 and 16 would not have been obvious over the reference.

Claim 15, 21 and 22 depend directly from claim 14, and thus also would not have been obvious over the reference.

Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

## V. Conclusion

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that the objection and rejections set forth by the Examiner have been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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